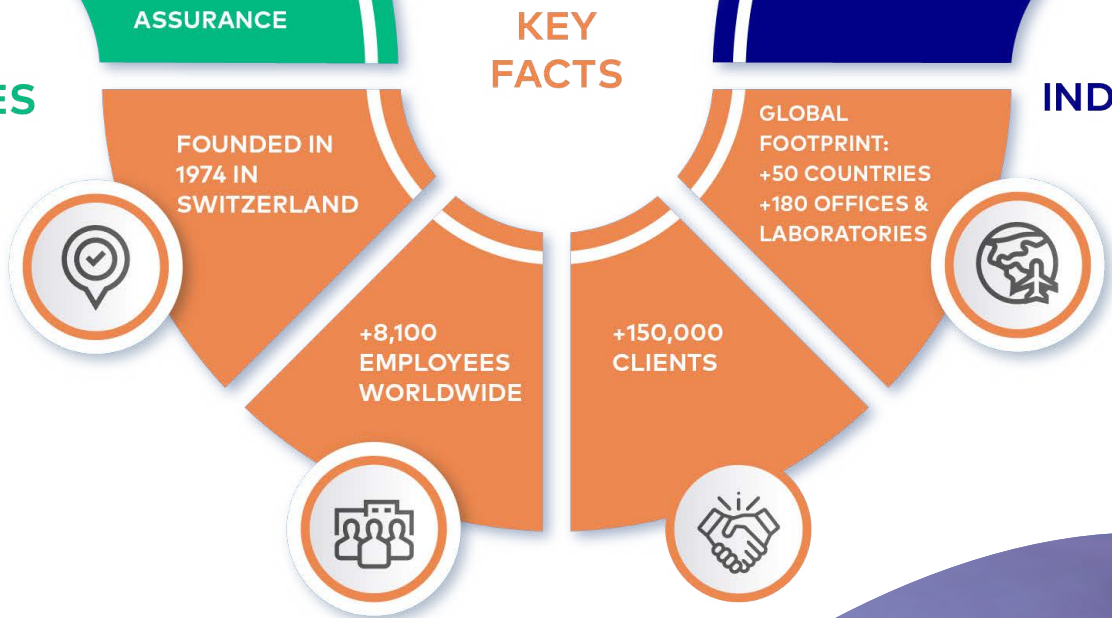


A composite image featuring a woman in a white lab coat and glasses holding a round-bottom flask with yellow liquid. In the foreground, a hand in a blue glove pours liquid from a brown bottle into a machine with several white-capped vials. The background shows a laboratory setting with shelves of bottles and a rack of test tubes. A large blue and teal graphic element curves across the left side of the image.

COTECNA PHARMA

Discover the full potential services intended to ensure the Quality of your Pharmaceutical products using state-of-art equipment and techniques.

Cotecna is a global provider of testing, inspection & certification services.



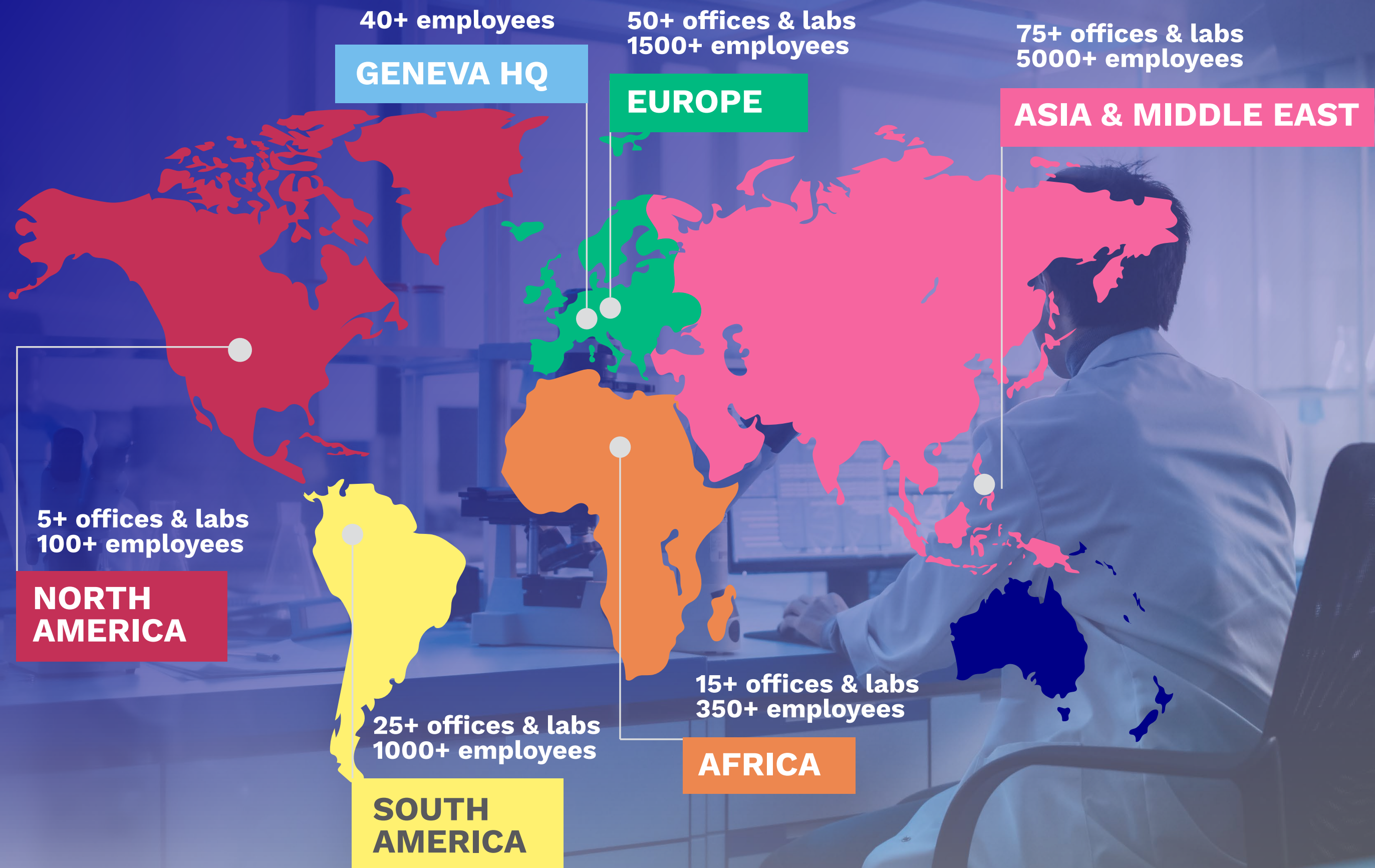
We **DREAM** of being your essential partner for TIC services by differentiating ourselves through technical expertise, innovation, proximity, and reactivity.

We **DARE** to act as challengers by taking risks to build our company and offering you solutions tailored to your needs.

We **DELIVER** on our customer promise, which creates credibility in our abilities.



Our Global Presence





Pharma Services

Cotecna Pharma provides a specialized form of laboratory analysis focused on determining the accuracy, strength, and weaknesses of pharmaceutical products. Pharma testing helps you determine the potency, efficacy, and proper dosage and use of your products, thus ensuring the health and safety of users.

Pharma Product & Scope

Cotecna’s Pharma Testing capabilities include the testing of different product categories



Raw Materials



Active Pharmaceutical Ingredients (APIs)



Finished Products



Medical Devices



Excipients



Bulk Drugs



Primary Packaging Materials



Ayush products



Cosmetics



Personal care products



Home care products



Dyes & Dye Intermediates

Inspection and testing services includes:

- > Assay
- > Impurities
- > Residual Solvents
- > Heavy Metals
- > Identification
- > General physical parameters
- > Microbial limit test
- > Microbiological Assay
- > Pathogens
- > BET
- > PET
- > Sterility
- > Cleaning validation pharmaceutical products as per pharmacopoeias

Analytical Portfolio

Cotecna labs are proficient in testing pharma products for contaminants, nitrosamines, pesticides, elemental impurities, pyrrolizidine alkaloids, pharmacopoeia methods, assay & impurities, stress test studies, residual solvents, and stability studies.

The Cotecna Pharma analytical portfolio includes:

- | | | |
|--|---|---|
| > Analytical Activities (Chemical/ Physical Microbiological Tests) | > Analytical Support for Process Validation | > Analytical Support on Primary Packaging Material choice |
| > Protocol study | > Investigation and support on Root Causes Analysis | > Full Service for ongoing stability studies (zone I, II, IV) |
| > Cleaning validation | > API suppliers auditing | > Identification of impurities |
| > Annual product review | > Method validation (According to ICH Q2 (R1)) | > Residual test study according to USP |
| > API titration according to specification limit | > Stress test study | |
| > Stability study (According to ICH guidelines ICH Q1) | | |



Cotecna Pharma Laboratories



Neotron offers a comprehensive “under one roof” service model at its state-of-the-art laboratory in Modena, Italy. Neotron Pharma is a specialized GMP division dedicated to providing analytical services for the pharmaceutical sector, covering APIs, drugs, excipients, and raw materials.

Accreditation	Accreditation Body
ISO/IEC 17025: 2017	Accredia
GMP certificate	AIFA IT/191/H/2025 issue 12/11/2025
Agenzia Italiana del Farmaco (AIFA) approved	AIFA N° aM-160/2025 issue 12/11/2025
FDA U.S Food & Drug Administration – facilities inspected	DUNS Number 43-916-5733 FEI 3011749590
Ministry of Health – Veterinary drugs	NBF/26/2024/V issue 24/04/2024
Ministry of Health – Drugs and psychotropic substances	D.D. n° 326/2025 issue 22/07/2025 exp. 22/07/2027



Neutron Pharma Scope

Neutron provides GMP compliant testing across a wide range of pharmaceutical products and related materials.

1. Active Pharmaceutical Ingredients (APIs)

Comprehensive chemical, biochemical, and microbiological analyses on APIs as part of quality control and development workflows.

2. Excipients

Testing of excipients used in drug formulations, assessing purity, identity, and potential contaminants.

3. Finished Pharmaceutical Products

Testing covers finished products across dosage forms (e.g., tablets, powders, liquids), evaluating identity, impurities, metals, solvents, and stability parameters.

4. Primary Packaging Materials

Packaging materials in contact with pharmaceuticals, including:

- > Containers
- > Closures
- > Other contact surfaces

Neutron assess extractables, leachables, compatibility, and safety.

5. Raw Materials Used in Pharmaceutical Manufacturing

We analyze raw materials used upstream in manufacturing, ensuring compliance with purity and safety specifications.

6. Pharmaceutical Packaging Safety (Extractables & Leachables Testing)

Neutron conducts:

- > Extractables studies
- > Leachables studies (targeted & untargeted)
- > Toxicology evaluations
- > Risk assessments

Analytes include VOCs, SVOCs, NVOCs, elemental impurities, and ions

7. Hemp & THC/CBD Finished products

Neutron provides GMP-level testing for:

- > Medicinal cannabis products
- > Cannabis magistral preparations
- > CBD oils
- > Botanical extracts

Tests include:

- > Assay for CBD and THC ($\Delta 8$ / $\Delta 9$)
- > Impurities Contaminants (EI, Pesticides, Mycotoxins)
- > Terpene profiling
- > Pesticides
- > Mycotoxins
- > Residual solvents
- > Heavy metals
- > DAC monography for Cannabidiol
- > Cannabinoids
- > Method validation for Assay and Impurities on FP

The laboratory supports customers from an analytical point of view, requesting appropriate ministerial authorizations for the handling of substances, throughout the supply chain from the raw material to the finished product.

ICHQ 3D Elemental Impurities Analytical Proposal

Determination of Elemental Impurities, in accordance with what is reported in tables 1, 2a, 2b and 3 of ICHQ3D

ICP-MS | ICP-OES | AAS

1. Screening
2. Method Validation
3. Pharmacopoeia analytical approach

Nitrosamines

Supporting customers for screening activities, validation on API, Drugs or excipients for elemental impurities and nitrosamine residues

GC-MS | HPLC-MS | HPLC- QToF

1. Screening (Limited/Semi-quantitative)
2. Method Validation (Quantitative)

Nitroso APIs focus

As reported in the latest revision EMA/409815/2020 Rev. 17 of 28 July 2023, the regulatory authority has updated the list of Nitrosamines to be monitored by also introducing Nitroso APIs and the relative limit for this molecule.

1. Supplying of Nitros STD
2. Set up of Nitros STD and method (R&D)
3. Screening and Method Validation

Extratable Study
Controlled extractions of materials/components
Toxicology evaluation on Extractables Data > AET
AET (Analytical Evaluation threshold)
Method Optimization
A leachables method to be optimized
Leachables Study
A leachables/simulation study with final product
Toxicology Review
Final tox assessment of leachables compounds found with toxicological

ICH,
ISO 10993-18,
USP 1663/1664,
USP 665/1665,
PQRI,
BPOG

Packaging materials are never 100% inert and they can change substances through various reactions mechanisms

The interaction of pharmaceutical products with packaging is an important topic in the plan of pharma product development.

Contaminants on Herbals

Controls of contaminants on excipients or herbal drug products according to GMP standards

1. Pesticides residues according to Ph.Eur 2.8.13
2. Elemental impurities according to ICH Q3D
3. Pyrrolizidine Alkaloids (28 molecules) in-house method
4. Aflatoxins (B1,B2,G1,G2) in-house method
5. Ochratoxins in-house method

Neutron Stability Studies

Accelerated or Long-term stability studies

7 Chambers for climatic zones I, II, IV according to ICH Q1 A (R2):

40°C ± 2°C	75% ± 5% U.R.
30°C ± 2°C	65% ± 5% U.R.
25°C ± 2°C	60% ± 5% U.R.
30°C ± 2°C	75% ± 5% U.R.



Neutron Specialty Equipment

- > Dissolutor
- > Disaggregator
- > Hardness tester
- > Spectrofotometer
- > K.F, Densimeter
- > Viscometer
- > Mastersizer
- > HPLC and UPLC detectors (DAD, refractive index, IR, Fluorimeter, Light scattering, MSMS, Detector TOF)
- > Ion Chromatography (Dionex)
- > GC area detectors (FID, ECD, HS-MS, MSMS)
- > ICP-OES
- > ICP-MS
- > AAS

Cotecna Pharma Laboratories

cotecna.com



Shiva Analyticals specializes in detailed analytical solutions through its state-of-the-art laboratory and exceptional team. Shiva's advanced pharmaceutical product testing laboratory in Bangalore, India, delivers cGMP compliant and USFDA approved analytical services for clients in

Accreditation	Accreditation Body
ISO/IEC 17025: 2017	National Accreditation Board for Testing and Calibration Laboratories (NABL)
Facility audited by USFDA in 2007 and 2016, FEI 3006192929, DUNS N° 91-844-1911	United States- Food and Drug Administration (USFDA)
Testing License (Form-37)	Karnataka Drugs Control Department
Medical Devices Testing License (MD-40)	Central Drugs Standard Control Organisation (CDSCO)
ISO 45001 : 2018	LRQA (Lloyd's Register Quality Assurance)
AS 9100	LRQA (Lloyd's Register Quality Assurance)
NADCAP Accreditation	NADCAP (National Aerospace and Defense Contractors Accreditation Program)

COTECNA



Shiva Analyticals Pharma Scope

Shiva Analyticals offers cGMP compliant, USFDA approved pharmaceutical testing services. Their testing scope spans the entire pharmaceutical value chain.

1. Raw Materials

Testing raw materials used in pharmaceutical manufacturing to ensure they meet identity, purity, and safety requirements.

2. Excipients

Shiva conducts pharmacopeial and regulatory testing on excipients used in drug formulations.

3. Active Pharmaceutical Ingredients (APIs)

We are cGMP-certified to analyse APIs for assay, impurities, heavy metals, residual solvents, and more.

4. Bulk Drugs & Intermediates

Full regulatory quality control on bulk drugs and intermediates before they move into dosage-form production.

5. Finished Pharmaceutical Products

Testing finished dosage forms including tablets, capsules, injectables, etc. according to pharmacopeial standards (USP, IP, EP, JP, BP).

6. Herbal Pharmaceutical Products

Analysis of herbal-based pharmaceutical products for identity, purity, contaminants, and regulatory compliance.

7. Medical Devices

Analytical testing for certain medical devices as part of regulatory compliance.



Shiva Analyticals Key Specialized Pharmaceutical Tests

Impurity Testing

- > Genotoxic impurities
- > Nitrosamine impurities
- > Azido impurities

Heavy Metals & Elemental Impurities

Using ICP-MS, ICP-OES, AAS.

Residual Solvents

By GC and headspace methods.

Stability Studies

ICH compliant stability testing for raw materials, APIs, and finished products.

Extractables & Leachables

Testing for packaging-product interactions.

Dissolution, Cleaning Validation & Method Validation

Comprehensive analytical method development and validation services under ICH guidelines.



Shiva Pharma Service Scope

The Shiva facility is registered and site self-identified with USFDA

Data Management handled through Agilent Open Lab ECM Software

- > Complete audit trails for each data acquisition software
- > Auto back-up of data to server through programmed schedulers
- > Multiple back-ups of data in PC, server, as well as magnetic tapes
- > Encrypted data in server and tapes to ensure data security

Workflow management through Caliber LIMS 3.2.1

- > Each batch of sample is traceable from its registration until archival/disposal
- > Demarcation with unique storage locations for pre and post analysis of sample

Dedicated cGMP areas with access controls for authorised personnel (second floor)



Extractable & Leachable Studies

Extractable and Leachable Studies on Primary, Secondary & Tertiary packaging components including Gum and Ink migrations Studies for:

- > Ophthalmic Solutions
- > Inhalation Aerosols and Sprays
- > Injections and Injectable Suspensions
- > Inhalation Powders & Solutions
- > Sterile Powders and Powder for Injection
- > Transdermal Ointments and Patches
- > Topical Powders, Solutions & Suspensions
- > Topical and Lingual Aerosols
- > Oral Powders, Solutions & Suspensions
- > Oral Tablets and Oral Hard & Soft Gelatin Capsules



R&D Services

Stability Studies as per ICH Guidelines

- > Long-term stability at 25°C / 60% RH,
- > Intermediate stability at 30°C / 65% RH
- > Accelerated stability at 40°C/ 75% RH
- > Forced Degradation - Photo Stability Chamber

Analytical Method Development & Validation

- > Assay
- > Related Substances
- > Residual Genotoxic Impurities
- > Residual Solvents / Volatile Organic Impurities
- > Residual elemental impurities
- > Wet Chemical Analysis
- > Content Uniformity



QC Testing

Pharmacopoeia testing of Raw Materials, Intermediates & Finish Products
Products Tested as per USP, BP, EP, IP Methods and Customers Requirements

Products Tested

- > Tablets
- > Capsules
- > Eye drops
- > Syrups etc.

Test Parameters

- > Identification
- > Physical parameters
- > Assay test
- > Related substances
- > Impurity profiling
- > Disintegration test



Packaging Material & Medical Devices Testing

Residual Ethylene Oxide Test

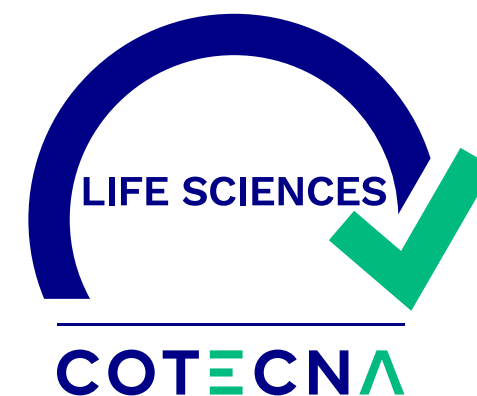
- > Ethylene Oxide, a carcinogenic gas used for sterilisation needs to be checked for its absence in medical devices
- > Evaluated using GC-HSS-FID along with Ethylene Glycol (EG) and Ethylene Chlorohydrin (ECH)



Shiva Speciality Equipment

- > LC-MSMS Triple Quad
- > GC-MSMS Triple Quad Purge & Trap
- > ICP MS
- > ICP OES
- > AAS
- > GC-Head Space GC-Dual FID Autosampler/Manual
- > UV-VIS Spectrophotometer
- > ATR-FTIR
- > Dissolutor
- > HPLC with UV-VIS'
- > RI
- > DAD
- > FLD
- > VWD
- > XRF
- > BET

Cotecna Pharma Laboratories



Cotecna Life Sciences specializes in detailed analytical solutions through its state-of-the-art laboratory and exceptional team. Cotecna Life Sciences pharmaceutical product testing laboratory in Mumbai, India (Maharashtra) delivers FDA approved analytical services for clients in the industry.

Accreditation	Accreditation Body
ISO/IEC 17025: 2017	NABL (in process)
Approved by Maharashtra Drug Control Department (FDA) for Drugs and Cosmetics	MH/106294 Date 20-05-2025
Approved by Maharashtra Drug Control Department (FDA) for AYUSH	



Cotecna Life Sciences Pharma Scope

Cotecna Life Sciences provides comprehensive, globally compliant pharmaceutical testing services covering the full lifecycle of pharma products.

Pharma Product Categories Scope

- > Raw materials
- > Excipients
- > Active Pharmaceutical Ingredients (APIs)
- > Bulk drugs
- > Finished pharmaceutical products
- > Herbal products
- > Medical devices
- > Primary packaging materials (e.g., container–closure systems)

Types of Analyses

Cotecna Life Sciences laboratories perform:

- > Impurity testing incl. nitrosamines, elemental impurities, pesticides
- > Pharmacopoeial testing (USP, EP, IP, JP, BP)
- > Assay & impurity profiling
- > Residual solvent testing
- > Stability studies (ICH Q1)
- > Method development & validation (ICH Q2)
- > Cleaning validation
- > API supplier audits & root cause investigations

Testing Capabilities

Pharmaceutical testing services include:

- > Chemical testing (assays, impurities, contaminants)
- > Microbiological testing
- > Instrumental analysis (HPLC, GC, ICP, etc.) for impurity profiling, heavy metals, residual solvents
- > Regulatory testing ensuring compliance with national & international pharma standards



Cotecna Life Sciences Specialty Equipment

- > HPLC (Waters 6 Nos. and Agilent 4 Nos. with UV Vis, PDA, RI Detector) ICP OES (Perkin Elmer)
- > GC (4 units, two with Head Space facility and two FID)
- > HPTLC (Camag)
- > FTIR with ATR facility (Shimadzu)
- > UV / VIS Spectroscopy (Shimadzu)
- > Dissolution Tester (Electro Lab 3 Nos, Lab India 1 Nos Lab India with Autosampler 1 No.) Brookfield Viscometer (Brook field) (RV, LV, with Helipath)
- > Potentiometric titrations,
- > Fluoride,
- > Disintegration,
- > Karl Fisher (K.F)
- > Laminar Air Flow,
- > Biosafety Cabinet
- > Autoclave
- > Air sampler
- > Incubators
- > Zone Reader

Why Choose Cotecna Pharma Services

Specialised and fully equipped state-of-the-art laboratories



Reliable and accurate reports

Proven expertise in testing a wide range of pharma products

Global network of offices and laboratories for local support

Request an Analysis

To learn more about our Pharma Testing services, or to request a quote for your business please don't hesitate to contact us.

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